

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert P. Auerbach on July 21, 2009.

The application has been amended as follows:

Claim 1: A method of manufacturing an implantable medical device, comprising:
purifying a polymer by:
introducing the polymer into ~~an extruder~~ ~~a mixing apparatus~~;
introducing a fluid into the ~~extruder~~ ~~mixing apparatus~~;
mixing the fluid with the polymer;
removing at least a volume of the fluid from the ~~extruder~~ ~~mixing apparatus~~ such that an impurity is completely or at least partially removed with the fluid; and
collecting the polymer after removal of the impurity; and
coating an implantable medical device with the purified polymer, or fabricating the implantable medical device with the purified polymer;
wherein the fluid is of a type to physically entrap the impurity without dissolving the impurity or the fluid is of a type to dissolve the impurity.

Claim 3: The method of Claim 1, wherein the ~~extruder~~ ~~mixing apparatus~~ is selected from the group consisting of a single screw extruder, an intermeshing co-rotating extruder and a counter-rotating twin-screw extruder.

Cancel claim 7.

Claim 8: The method of Claim 1, the method further comprising introducing a second fluid into the ~~extruder mixing apparatus~~, and mixing the second fluid with the polymer and removing the second fluid and an impurity from the ~~extruder mixing apparatus~~.

Cancel claims 11-12.

Claim 13: A method of manufacturing a coating for an implantable medical device, comprising:

- (a) purifying a thermoplastic polymer, the purifying including introducing the polymer into an extruder, introducing a fluid into the extruder, mixing the fluid with the polymer, ~~removing the impurity with the fluid~~, removing at least a portion of the fluid and an impurity from the extruder, and collecting the polymer after removal of the impurity; and
- (b) applying a composition to an implantable medical device, the composition including the purified polymer, a solvent and optionally a therapeutic agent; wherein the fluid is of a type to physically entrap the impurity without dissolving the impurity or the fluid is of a type to dissolve the impurity.

Cancel claims 14 and 19-22.

Claim 23: A method of manufacturing an implantable medical device, comprising: purifying a polymer by: introducing the polymer into an ~~extruder a mixing apparatus~~; introducing a fluid into the ~~extruder mixing apparatus~~, the fluid selected from the group consisting of FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, dimethyl sulfoxide, and combinations thereof; mixing the fluid with the polymer;

removing at least a volume of the fluid from the extruder mixing apparatus such that an impurity is completely or at least partially removed with the fluid; and
collecting the polymer after removal of the impurity; and
coating an implantable medical device with the purified polymer.

Claim 25: The method of Claim 23, wherein the extruder mixing apparatus is selected from the group consisting of a single screw extruder, an intermeshing co-rotating extruder and a counter-rotating twin-screw extruder.

Claim 29: The method of Claim 23, the method further comprising introducing a second fluid into the extruder mixing apparatus, and mixing the second fluid with the polymer and removing the second fluid and an impurity from the extruder mixing apparatus.

Claim 31: A method of manufacturing an implantable medical device, comprising:
purifying a polymer by:
introducing the polymer into an extruder a mixing apparatus, the polymer having an impurity;
introducing a first fluid into the extruder mixing apparatus, the first fluid acting as a solvent for the impurity;
mixing the first fluid with the polymer;
removing at least a volume of the first fluid from the extruder mixing apparatus such that the impurity is at least partially removed with the first fluid;
introducing a second fluid into the extruder mixing apparatus, the second fluid acting as a non-solvent for the impurity;
mixing the second fluid with the polymer;
removing at least a volume of the second fluid from the extruder mixing apparatus such that the impurity is at least partially removed with the second fluid; and
collecting the polymer after removal of the impurity; and
coating an implantable medical device with the collected polymer, or fabricating the implantable medical device with the collected polymer, wherein the second fluid is not the same as the first fluid.

Claim 32: The method of Claim 31, wherein after the first fluid has removed the impurity, exposing the first fluid to a temperature equal to or greater than the boiling temperature of the first fluid at ambient pressure prior to removing the first fluid from the extruder mixing apparatus.

Claim 33: The method of Claim 31, wherein after the second fluid has removed the impurity, exposing the second fluid to a temperature equal to or greater than the boiling temperature of the second fluid at ambient pressure prior to removing the second fluid from the extruder mixing apparatus.

Claim 35: The method of claim 1, further comprising exposing the fluid to a temperature equal to or greater than the boiling temperature of the fluid at ambient pressure prior to removing the fluid from the extruder mixing apparatus.

Claim 36: The method of Claim 13, wherein the purifying further includes introducing a second fluid into the extruder mixing apparatus, and mixing the second fluid with the polymer and removing the second fluid and the impurity from the extruder mixing apparatus, wherein the second fluid is of a type that dissolves the impurity and the second fluid is not the same as the first fluid.

Claim 37: The method of Claim 13, further comprising exposing the fluid to a temperature equal to or greater than the boiling temperature of the fluid at ambient pressure prior to removing the fluid.

2. The following is an examiner's statement of reasons for allowance: the arguments presented on pg. 8-11 of the Appeal Brief is convincing.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is (571)272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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